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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 2

Application Number: 09/600,732
Filing Date: July 20, 2000
Appellant(s): SMITS ET AL.

Norman P Soloway
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on December 29, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 65-97 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,613,377	Yamazaki et al.	9-1986

5,660872 Van Loo et al. 8-1997

Van Den Ende et al. Fructan synthesizing and degrading activities in chicory roots (Cichorium intybus L.) during field-growth, storage and forcing, Plant Physiology, Vol. 149, (1996), pp. 43-50.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(i) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim 65 recites "partially or wholly falls outside conventional ones" which is unclear and indefinite because it is unclear what the outside conventional period refers to (that is, are there any outside periods that are included other than the said periods recited in the instant claim 65). Further the term conventional period is a relative term and according to the specification on page 14, "conventional climatological temperature conditions for growing and processing is meant to a period of less than 220 consecutive days immediately preceding the end of the processing of the roots, low temperature conditions have occurred which trigger the FEH gene in chicory roots to a significant extent". It is not clear whether the conventional period is meant to clarify inclusion of low temperatures and inclusion of triggering FEH gene.

(ii) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claim 65-78, and 89-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996).

Yamazaki et al. teach a method for processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column 11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9). Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27); obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot

water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49); production of fructoligosaccharides from inulin (see column 10, lines 36-56); fructooligosaccharides containing about 0-100% by weight of monosaccharides (see column 10, lines 51-56). However, Yamazaki did not teach the periods of seeding/growing/processing includes no triggering or production of fructan exohydrolase gene in chicory roots.

Van Den Ende et al. teach a process for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd , October 4th to October 25th, September 13th to December 6th (see page 44, column 1, paragraph 4) ; (iii) chicory roots stored at $+1^{0}$ C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraph 4) and (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraphs 1-4).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the method of growing and harvesting chicory roots as taught by Van Den Ende et al. to achieve expected advantage of developing a process for manufacturing chicory inulin from chicory roots under proper climatological temperatures because Van Den Ende et al. states that "seasonal changes in the biochemistry of

fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). An ordinary practitioner would have been motivated to combine the method of Yamazaki et al. with the method of Van Den Ende et al. by incorporating the proper climatological conditions which partially or wholly falls outside conventional seeding and growing conditions in order to achieve the expected advantage of developing an improved process of preparing chicory inulin.

B. Claims 79-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) as applied to claims 65-78, 89-97 above, and further in view of Van Loo (USPN. 5,660,872).

Van Loo et al. teach a method for producing inulin free with low molecular weight polysaccharides (sugars) wherein Van Loo et al. disclose that the method comprises isolation of inulin from chicory roots with hot water to obtain aqueous solution of inulin, purification of inulin followed by concentrating the inulin solution by partial removal of water (see column 11, lines 47-62); the method also comprises obtaining inulin free of mono-and disaccharides, drying inulin to a particulate form (see column 12, lines 1-67, column 13, lines 1-17). Van Loo et al. further discloses obtaining inulin free of low molecular weight polysaccharides with DP greater than 5 (column 5, lines 5-44).

Yamazaki et al. teach a method for processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column 11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9). Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27); obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49); production of fructoligosaccharides from inulin (see column 10, lines 36-56); fructooligosaccharides containing about 0-100% by weight of mono saccharides(see column 10, lines 51-56).

Van Den Ende et al. teach a process for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclsose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd , October 4th to October 25th, September 13th to December 6th (see page 44, column 1, paragraph 4) ; (iii) chicory roots stored at +1^{0} C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraph 4) and (iii) inulin was obtained with a

standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraphs 1-4).

However, neither Yamazaki et al. nor Van Den Ende et al. teach the production of inulin free of monomeric saccharides, dimeric saccharides and oligofructose.

Van Loo et al. teach a method for producing inulin free with low molecular weight polysaccharides (sugars) wherein Van Loo et al. disclose that the method comprises isolation of inulin from chicory roots with hot water to obtain aqueous solution of inulin, purification of inulin followed by concentrating the inulin solution by partial removal of water (see column 11, lines 47-62); the method also comprises obtaining inulin free of mono-and disaccharides, drying inulin to a particulate form (see column 12, lines 1-67, column 13, lines 1-17). Van Loo et al. further discloses obtaining inulin free of low molecular weight polysaccharides with DP greater than 5 (column 5, lines 5-44).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the method of growing and harvesting chicory roots as taught by Van Den Ende et al. and the method of producing polydispersed saccharides as taught by Van Loo et al. to achieve expected advantage of developing a process for manufacturing improved Grade chicory inulin from chicory roots under proper climatological temperatures and because Van Den Ende et al. states that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from

high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Further, Van Loo et al. states that "the degree of polymerization (DP) has direct effect on the solubility of inulin and varies according to the conditions of harvesting chicory roots and saccharides comprise a DP greater than 2 would result in coloration, difficulty in solubility and crystallize at temperatures below 65^0 C" (see column 1, lines 55-67, column 2, lines 1-22). An ordinary practitioner would have been motivated to combine the method of Yamazaki et al. with the method of Van Den Ende et al. by incorporating the proper climatological conditions and production of inulin free of polydispersed saccharides in order to achieve the expected advantage of developing a method for production of improved grade inulin.

(11) Response to Argument

(i) With regard to the rejection of claims 65-97 under 35 USC 112, second paragraph, arguments have been considered and found persuasive and the rejection will fall.

(ii) With regard to the rejection of claims 65-78, 89-97 under 35 USC 103(a) as being obvious over Yamazaki et al. in view of Van Den Ende et al., Applicants' arguments on page 11 of the appeal brief, that the rejection of claims 65-78 and 89-97 as obvious over Yamazaki et al. in view of Van Den Ende et al is in error and the assertion that the invention on appeal relates to biological plant systems which, by their nature are notoriously unpredictable, and the present claimed invention concerns natural products which are by their nature, unpredictable, are fully considered. Applicants further argue (on page 12 of the appeal brief) that the prior art teaches away from seeding chicory and having chicory in the first growing phase possibly exposed to low temperature conditions which trigger FEH gene and the prior art is not obvious at all that

chicory could be cultivated (including seeding-growing-harvesting-storing and processing) during other periods and under other climatological temperature conditions than the ones from the conventional cultivation of chicory. Applicants' arguments regarding the conventional growing conditions is fully considered but found not persuasive because first, Applicants argue in general the climatological conditions for Northern Europe and asserts that the chicory is conventionally seeded at the end of the season with frost (depending from the occurring weather conditions from about March 15 to May 14). However, the prior art (Van Den Ende et al.) teaches seeding of Cichorium intybus (chicory) on June 1 and the growing and processing periods ranges form 98 days (July 26th to November 3rd), 120- 145 days (June 1-October 4th, and June 1st to October 25th). Analysis of inulin degradation was carried out during September 13th to December 6th (end of frost season). The analysis of inulin in different growing and processing periods indicates the inulin synthesis and degradation, include the periods (July 26th to August 20th) (no frost season), where the higher DP inulin was produced. The broad limitations recited in the instant claim 65 does not exclude any day in a year and overlaps with the periods taught by Van Den Ende et al.

Further Appellants argue that there is no teaching or suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed.

Cir.1992). Thus the overlapping climatological conditions as claimed in the instant claims to improve the inulin production are obvious over Yamazaki et al. in view of Van den Ende et al.

In response to Appellants' argument on page 15, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellants argue on page 15 of the brief, that the weather conditions in Belgium are different that of Brussels and argue that the temperatures are not the same because of the mass of buildings, roadways and heat generating sources in Brussels, which is expected to raise the temperature in Brussels. Appellants argue that the reliance on In re Cruciferous Sprout Litigation is improper. The arguments are not persuasive because the nature driven climatological conditions would not vary drastically as stated by the Appellants since the distance between the rural area (Belgium, Herverlee) and the metropolitan Brussels is only 14 kilometers. Further it is noted that the Appendix B and C submitted by the Appellants did not disclose any particular temperature for Herverlee. Thus the reliance on the In re Cruciferous Sprout Litigation is proper.

In response to the Applellants arguments on page 16 of the Brief, regarding non-conventional process parameter/conditions, it is noted that the claims do not recite any non-conventional cultivating conditions for chicory inulin production.

In response to the Appellants arguments on page 17, regarding no teaching of chicory roots for inulin production, may appropriately be seeded, grown and processed under conditions where low temperature conditions/ frost can occur, However, it is noted that Appellants agree that Van Den Ende et al. disclose that low temperature be avoided for the cultivation of chicory roots processing includes storage of roots, which was carried out at $+1^0$ C, suggesting no effect of low temperatures. Further the prior art indicates that a decrease in SST/FFT ratio probably enhances competitive inhibition by sucrose as an acceptor for FFT and suggests that FFT might then start to depolymerize larger fructans to smaller ones. The analysis of inulin in different growing and processing periods indicates the inulin synthesis and degradation, which include the periods (July 26^{th} to August 20^{th}) where the higher DP inulin was produced. Therefore the effect of low temperatures on inulin degradation is a limiting parameter which is obvious and known from the prior art cited. Thus the limiting parameter (low or frost temperatures) is known at the filling of the instant patent application and it is prima facie obvious to avoid such conditions in the cultivation of chicory roots. Thus it is prima facie obvious to optimize the cultivating conditions not to fall in the low temperature conditions.

Finally, Appllents arue that the subject matter of the present invention is clearly unexpected in view of the teachings of Van Den Ende et al. However, as MPEP 716.02 (d) states "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)". Here,

the unexpected result for cultivating chicory roots is not commensurate in scope with the independent claim 65, which comprises a range of cultivating periods which include any day in a year.

With regard to the rejection of claims 79-88 as obvious over Yamazaki et al. in view of Van Den Ende et al. and further in view of Van Loo et al., as discussed above, the base claim 65 is maintained under obviousness rejection, and hence the teachings of Van Loo et al. in combination with the teachings of Yamazaki et al. and Van Den Ende et al, make the claims obvious.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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February 18, 2004

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